DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1 – 22 in the reply filed on August 17, 2009 is acknowledged, as well as the species election recited in claim 3.

2. Claims 4, 5, and 23 – 47 are acknowledged as withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions or species.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

On page 19, line 12, the "detection system 10" is disclosed with respect to Figure 1, however, this reference number is not displayed within Figure 1.

On page 21, line 22, the "detection system 110" is disclosed with respect to Figure 2, however, this reference number is not displayed within Figure 2.

On page 28, line 32, the "opposing surface 260d" and "channels 262d" are disclosed with respect to Figure 4D, however, these reference numbers are not displayed within Figure 4D.

On page 29, line 22, the "opposing surface 260f" is disclosed with respect to Figure 4F, however, this reference number is not displayed within Figure 4F.

On page 32, lines 11-12, the "central axis 563" is disclosed with respect to Figure 7, however, this reference number is not displayed within Figure 7.

On page 35, line 19, the "housing 612" is disclosed with respect to Figure 8, however, this reference number is not displayed within Figure 8.

On page 46, line 29, the "housing 1695" is disclosed with respect to Figure 10C, however, this reference number is not displayed within Figure 10C.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description:

Figure 8C displays reference numbers **651a** and **651b**, which are not disclosed in the specification.

Figures 10A and 10B display reference number **895**, which is not disclosed in the specification.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet

submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The disclosure is objected to because of the following informalities:

On pages 6-7, 11, 18, 21, 23, 35, 49 and 51, blank lines are included for previously unknown application numbers.

On page 24, line 23, "Fig. 1" is disclosed, however it is Figure 3 that is being discussed in this section of the specification.

On page 26, line 27, the "detection chamber" is disclosed as reference number "30," however, the "detection chamber" is previously and subsequently labeled as reference number "230."

On page 37, line 31, the term "chamfer" is disclosed, which appears to be an incorrect spelling of the term "chamber."

On page 46, line 7, the "chamber" and "reagent" are labeled as reference number "686" and "692," respectively, which is incorrect. These should be labeled as reference numbers "886" and "892," respectively (see also line 17, for incorrect labeling of "reagent 692").

Appropriate correction is required.

Claim Objections

6. Claims 1, 11 and 12 are objected to because of the following informalities:

Claim 1 fails to include the term "and" between the recitations of the first and second "means" (i.e. the "and" should be included at the end of line 11).

Claim 11 recites the phrase "proximate the detection surface," which should be "proximate **to** the detection surface" in order to recite correct grammar.

Claim 12 recites the phrase "further comprising **a one or more sealed modules**," which should be "further comprising **one or more sealed modules**" in order to recite appropriate grammar.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 11, recites the term "the shear horizontal surface acoustic wave sensor," which lacks antecedent basis.

Claim 7 recites the term "the cartridge," which lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1 – 3, 7, and 12 – 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Hunt et al. (US 2008/0138797).

Hunt et al. teach a detection system for detecting a target substance (biological analyte), the system comprising:

a surface acoustic wave sensor comprising a detection surface;

a binding (capture) agent 220 located on the detection surface, wherein the binding agent is capable of selectively attaching the target substance to the detection surface;

a detection chamber 102 located within an interior volume of a housing, the detection chamber comprising a volume defined by the detection surface and an opposing surface spaced apart from and facing the detection surface, wherein the opposing surface of the detection chamber comprises a flow front control feature, including transducers and/or binding agents;

a reservoir 108 (waste chamber) located within the interior volume of the housing, the reservoir in fluid communication with the detection chamber;

means for driving the shear horizontal surface acoustic wave sensor; and

means for analyzing data from the surface acoustic wave sensor to determine if target substance is coupled to the binding agent (see Figures 1 and 2; and paragraphs [0009], [0010], [0022]-[0029], [0032], [0033], [0036], and [0040]).

With respect to Applicant's claim 2, the surface acoustic wave sensor can be a shear horizontal surface acoustic wave sensor (see paragraph [0026]).

With respect to Applicant's claim 3, the flow front control feature can comprise transducers or binding agents (discrete structures protruding from and separated by a land area) on the opposing surface of the detection chamber (see Figure 2; and paragraph [0036]).

With respect to Applicant's claim 7, the housing further includes a port 206 (capillary structure) located between the detection chamber and the reservoir 108 (see Figure 2; and paragraph [0040]).

With respect to Applicant's claims 12 – 15, the system includes one or more sealed reservoirs 103 (modules), wherein each reservoir comprises an exit port attached to the housing through one or reservoir module ports 206 that open into the interior volume of the housing, wherein at least one reservoir contains a liquid isolated from the interior volume of the housing, wherein said liquid can comprise a selected reagent or lysing reagent (see Figures 1 and 2; and paragraphs[0029], [0032], [0033], and [0040]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1 – 3, 6 – 8 and 12 – 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Warthoe et al. (US 2004/0072208) in view of Buechler (US 6,156,270).

Warthoe et al. teach a sensor system for detecting a target biological analyte, the system comprising:

a surface acoustic wave sensor comprising a sensor (detection) surface;

a binding ligand (capture agent) located on the sensor surface, wherein the binding ligand is capable of selectively attaching the target biological analyte to the sensor surface;

a detection chamber located within an interior volume of a device housing, the detection chamber comprising a volume defined by the sensor surface and an opposing surface spaced apart from and facing the detection surface;

a waste reservoir (chamber) located within the interior volume of the device housing, the waste reservoir in fluid communication with the detection chamber;

means for driving the shear horizontal surface acoustic wave sensor; and

means for analyzing data from the surface acoustic wave sensor to determine if target biological analyte is coupled to the binding ligand (see paragraphs [0017], [0018], [0022],

[0023], [0028], [0062], [0068], [0074]-[0076], [0089], [0090], [0100], [0143], [0144], [0150], [0153], and [0172]).

However, Warthoe et al. fail to teach the inclusion of flow front control features, which comprise discrete structures protruding from and separated by a land area, on the opposing surface of the detection chamber.

Buechler teaches a diagnostic device for detecting the presence or amount of a target ligand in a sample, wherein the device comprises at least a sample addition reservoir 2, a reaction chamber 4, a diagnostic element 6, which includes a capture zone, and a used reagent reservoir 7 (i.e. waste chamber). The diagnostic element can comprise one of a plurality of different types of biosensor elements, including a surface acoustic wave sensor. Further, the structure of the diagnostic element comprises opposing surfaces 8 and 9, wherein at least one of the surfaces includes fluid control means 18, which are designed to control the flow of the reaction mixture in the device. More specifically, the flow control means causes the volume of the reaction mixture to flow over the capture zone of the diagnostic element at a rate which allows for optimum capture of reagents onto the capture zone (see Figures 1, 1D, and 2; column 3, lines 61-66; column 4, lines 49-63; column 7, lines 6-15 and lines 31-41; column 14, lines 54-60; and column 20, lines 42-52).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the system of Warthoe et al. an opposing surface of the detection chamber that comprises flow front control features as taught by Buechler because Buechler teaches the benefit of including flow control means 18 on an opposing surface of a diagnostic element comprising a capture zone, wherein the diagnostic element is part of a

biosensor system, because the flow control means control the flow of a reaction mixture within the device by causing the volume of the reaction mixture to flow over the capture zone of the diagnostic element at a rate which allows for optimum capture of reagents onto the capture zone.

With respect to Applicant's claim 2, Warthoe et al. teach that the surface acoustic wave sensor can be a shear horizontal surface acoustic wave sensor (see paragraphs [0061]-[0062]).

With respect to Applicant's claim 3, Buechler teaches that the flow control means can comprise discrete structures protruding from and separated by a land area on the opposing surface of the diagnostic element (see Figure 1D; and column 14, lines 54-60).

With respect to Applicant's claim 6, Buechler teaches that the used reagent reservoir (waste chamber) can include an absorbent material to contain the used reagent and prevent it from flowing backwards into the system (see column 20, lines 42-52; and column 21, lines 17-21).

With respect to Applicant's claim 7, Warthoe et al. teach that the housing further includes a capillary structure, such as a channel, located between the detection chamber and the other chambers or reservoirs, i.e. waste reservoir (see paragraphs [0144], [0150] and [0172]).

With respect to Applicant's claim 8, Buechler teaches the inclusion of a vent (see column 8, lines 55-57).

With respect to Applicant's claims 12 – 17, the system of Warthoe et al. includes one or more sealed modules, wherein each module comprises an exit port attached to the housing through one or more module ports that open into the interior volume of the housing, wherein at least one module contains a liquid isolated from the interior volume of the housing, wherein said

liquid can comprise a selected reagent or lysing reagent, and wherein at least two sealed modules can be connected together (i.e. first and second chambers) with a seal isolating the modules from one another and at least one means is provided for moving material located within at least one of the modules into the interior volume of the housing (see paragraphs [0100], [0113], [0117], [0143], [0144], [0150], [0152]-[0156], and [0175]-[0177]).

10. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Warthoe et al. (US 2004/0072208) in view of Buechler (US 6,156,270), as applied to claims 1 and 8 above, and further in view of Hodges et al. (US 2003/0180814).

The Warthoe et al. and Buechler references, which were discussed in the 103(a) rejection above, fail to teach the inclusion of a closure element operably attached to the vent.

Hodges et al. teach an immunosensor assay device, which comprises a reaction chamber 22, a detection chamber 38, and an aperture or vent 30 that is covered by a piercing layer. The vent allows for controlling the flow of fluid from the reaction chamber to the detection chamber, wherein when the vent, which is initially closed, is opened by means of a needle, trapped air within the system is released into the atmosphere allowing for the sample to flow from the reaction chamber and fill the detection chamber (see Figures 1 and 2; and paragraphs [0015], [0045], and [0059]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Warthoe et al. and Buechler a closure element attached to the vent as taught by Hodges et al. because Hodges et al. teach the benefit of including a piercing layer (i.e. closure element) over a vent provided within an immunosensor

device, wherein the device includes at least two chambers, in order to control the flow of fluid within the chambers of the device, wherein when the vent, which is initially closed, is opened by means of a needle, trapped air within the system is released into the atmosphere allowing for the sample to flow from one chamber and fill a second chamber.

11. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Warthoe et al. (US 2004/0072208) in view of Buechler (US 6,156,270), as applied to claim 1 above, and further in view of Beebe et al. (US 2003/0077836).

Warthoe et al. and Buechler further fail to teach that the device includes a fluid monitor operably connected to the housing.

Beebe et al. teach an apparatus for monitoring the environment within a microfluidic device, wherein the apparatus comprises a body and at least one channel for accommodating the flow of fluid therethrough. The apparatus further includes at least one monitor structure within the channel, wherein the monitor structures allows for detecting and monitoring any change, i.e. chemical, temperature or electrical, of the fluid flowing within the channel of the device (see Figures 1 and 6; Abstract; and paragraphs [0029], [0031] and [0041]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Warthoe et al. and Buechler a fluid monitor structure as taught by Beebe et al. because Beebe et al. teach the benefit of including at least one monitor structure within a channel of a microfluidic device in order to allow for detecting and monitoring any change, i.e. chemical, temperature or electrical, of the fluid flowing within the channel of the device.

12. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Warthoe et al. (US 2004/0072208) in view of Buechler (US 6,156,270), as applied to claim 1 above, and further in view of Ohman et al. (US 2005/0042766).

Warthoe et al. and Buechler further fail to teach the inclusion of a magnetic field generator capable of providing a magnetic field proximate the detection surface.

Ohman et al. teach a microfluidic system comprising a substrate and at least one flow path, wherein a sample fluid is applied to the substrate and flows along the at least one flow path. The system can further include a magnet arranged in or around the flow path(s) in order to trap and retain magnetic particles or substances at desired locations in the flow path. In addition, the magnetic particles can be coated with substances having a biological affinity for a particular target analyte (see Abstract; and paragraph [0069]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the detection surface of the device of Warthoe et al. and Buechler a magnet (i.e. magnetic field generator) as taught by Ohman et al. because Ohman et al. teach the benefit of including a magnet within a microfluidic system comprising a sample flow path in order to trap and retain magnetic particles or substances at desired locations in the flow path, wherein the magnetic particles can be coated with substances having a biological affinity for a particular target analyte.

13. Claims 18, 19, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Warthoe et al. (US 2004/0072208) in view of Buechler (US 6,156,270), as applied to claim 1 above, and further in view of Tisone (US 2006/0292304).

Warthoe et al. and Buechler fail to teach that the one or more modules include a plunger that is movable via an actuator operably coupled to the plunger, wherein movement of the plunger towards the exit port opens the exit seal such that material from the at least one module exits through the exit port into the interior volume of the housing.

Tisone teaches a method and apparatus for dispensing reagents onto a substrate, wherein the apparatus includes at least one pump 22 that includes a reagent for dispensing into the system and onto the substrate. The pump includes a plunger 64 that is operably coupled to an actuator. The plunger is moved axially in order to force reagent out of the pump housing and into an exit tube 70. The actuator is used in conjunction with the plunger in order to precisely regulate the amount and/or flow rate of reagent that is forced out of the pump housing (see Figures 1A, 1B, and 5; Abstract; and paragraphs [0016], [0018], [0019] and [0052]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device and modules of Warthoe et al. and Buechler a plunger and actuator operably coupled thereto as taught by Tisone because Tisone teaches the benefit of including a plunger within a housing chamber (i.e. module) containing a reagent, wherein the reagent is dispensed into a system comprising a substrate, and wherein the plunger is operably coupled to the actuator in order to move the plunger axially and force reagent out of the housing chamber, because the use of an actuator in conjunction with a plunger in a housing chamber containing a reagent allows for the precise regulation of the amount and/or flow rate of reagent that is forced out of the housing chamber via the plunger.

14. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Warthoe et al. (US 2004/0072208) in view of Buechler (US 6,156,270) and Tisone (US 2006/0292304), as applied to claims 18 and 19 above, and further in view of Beebe et al. (US 2003/0077836).

The Warthoe et al., Buechler and Tisone references, which were discussed in the 103(a) rejection directly above, fail to teach that the device includes a fluid monitor operably connected to the housing.

Beebe et al. teach an apparatus for monitoring the environment within a microfluidic device, wherein the apparatus comprises a body and at least one channel for accommodating the flow of fluid therethrough. The apparatus further includes at least one monitor structure within the channel, wherein the monitor structures allows for detecting and monitoring any change, i.e. chemical, temperature or electrical, of the fluid flowing within the channel of the device (see Figures 1 and 6; Abstract; and paragraphs [0029], [0031] and [0041]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Warthoe et al., Buechler and Tisone a fluid monitor structure as taught by Beebe et al. because Beebe et al. teach the benefit of including at least one monitor structure within a channel of a microfluidic device in order to allow for detecting and monitoring any change, i.e. chemical, temperature or electrical, of the fluid flowing within the channel of the device.

With respect to Applicant's claim 21, Tisone teaches the inclusion of a controller operably coupled to the actuator (see paragraphs [0052] and [0053]).

Conclusion

15. No claims are allowed.

16. The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

McGovern et al. (WO 00/68419) teach an apparatus for monitoring small-biomolecule interactions, wherein the apparatus comprises a surface wave acoustic biosensor, at least one detection surface comprising a plurality of binding agents, at least one chamber, and at least one inlet and outlet for introducing and removing fluid or gas to the chamber(s), respectively (see Figure 4; p5, lines 14-18; p7, lines 4-18; p17, lines 16-20; p18, lines 1-15; and pages 21-22).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE DIRAMIO whose telephone number is (571)272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 1641

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